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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,930	03/22/2001	Ellen Heber-Katz	00486.00006	1820

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EXAMINER	
LACOURCIERE, KAREN A	

ART UNIT	PAPER NUMBER
1635	5

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,930	Applicant(s) HEBER-KATZ, ELLEN	
	Examiner Karen Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 15-23, drawn to a method of increasing healing of a heart wound in a mammal by administering a small molecule thyroid hormone inhibitor, classifiable in class 514, subclass 1.

II. Claims 1, 6, 7, 9, 10 and 15-23, drawn to a method of increasing healing of a heart wound in a mammal by administering a polynucleotide which inhibits the expression of thyroglobulin, classified in class 514, subclass 44.

III. Claims 1, 6, 8, 9, 11 and 15-23, drawn to a method of increasing healing of a heart wound in a mammal by administering a polynucleotide inhibitor of thyroid stimulating hormone, classified in class 514, subclass 44.

IV. Claims 1, 12, 13 and 15-23, drawn to a method of increasing healing of a heart wound in a mammal by administering an antibody that specifically binds to thyroglobulin, classified in class 514, subclass 2.

V. Claims 1, 12 and 14-23, drawn to a method of increasing healing of a heart wound in a mammal by administering an antibody that specifically binds to thyroid stimulating hormone, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III and IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods, which are not used together, and which have different modes of operation.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group I comprise administering a small molecule thyroid hormone lowering agent, which operates by inhibiting the production of thyroid hormone by the thyroid, these agents are materially different than the methods of Group II, which require administration of a polynucleotide, and operate by inhibiting the expression of thyroglobulin by binding to mRNA encoding thyroglobulin.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group I comprise administering a small molecule thyroid hormone lowering agent, which operates by inhibiting the production of thyroid hormone by the thyroid, these agents are materially different than the methods of Group III, which require administration of a polynucleotide,

and operate by inhibiting the expression of thyroid stimulating hormone by binding to mRNA encoding thyroid stimulating hormone.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group I comprise administering a small molecule thyroid hormone lowering agent, which operates by inhibiting the production of thyroid hormone by the thyroid, these agents are materially different than the methods of Group IV, which require administration of an antibody, and operate by inhibiting thyroglobulin activity by binding to thyroglobulin protein.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group I comprise administering a small molecule thyroid hormone lowering agent, which operates by inhibiting the production of thyroid hormone by the thyroid, these agents are materially different than the methods of Group V, which require administration of an antibody, and operate by inhibiting thyroid stimulating hormone activity by binding to thyroid stimulating hormone activity.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and are drawn to materially different methods with different modes of operation. For example, the methods of Group II are drawn to methods wherein a polynucleotide, which binds to thyroglobulin mRNA is administered, and the methods operate by inhibiting the expression of thyroglobulin. The polynucleotides of Group II are materially different than the polynucleotides of Group III, which bind to mRNA encoding thyroid stimulating hormone, because the structure (ie. nucleotide sequence) is based on the sequence of the target mRNA. Additionally, the methods of Group III have a different mode of operation, because the methods of Group III operate by inhibiting the expression of thyroid stimulating hormone.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group II require the administration of a polynucleotide, which is composed of nucleotides, and operate by inhibiting the expression of thyroglobulin. This is materially different than the methods of Group IV, which require the administration of an antibody, which is composed of amino acids, and operate by inhibiting the activity of thyroglobulin.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group II require the administration of a polynucleotide, which is composed of nucleotides, and operate by inhibiting the expression of thyroglobulin. This is materially different than the methods of Group IV, which require the administration of an antibody, which is composed of amino acids, and operate by inhibiting the activity of thyroid stimulating hormone.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group II require the administration of a polynucleotide, which is composed of nucleotides, and operate by inhibiting the expression of thyroid stimulating hormone. This is materially different than the methods of Group IV, which require the administration of an antibody, which is composed of amino acids, and operate by inhibiting the activity of thyroglobulin.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with

different modes of operation. For example, the methods of Group III require the administration of a polynucleotide, which is composed of nucleotides, and operate by inhibiting the expression of thyroid stimulating hormone. This is materially different than the methods of Group V, which require the administration of an antibody, which is composed of amino acids, and operate by inhibiting the activity of thyroid stimulating hormone.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and are drawn to materially different methods with different modes of operation. For example, the methods of Group IV are drawn to methods wherein an antibody, which binds specifically to thyroglobulin, is administered and the methods operate by inhibiting the activity of thyroglobulin. This is different than the methods of Group V, wherein an antibody which specifically binds thyroid stimulating hormone is administered and the methods of Group V operate by inhibiting the expression of thyroid stimulating hormone.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1 and 15-23 are generic to Groups I-V. Additionally, claims 6 and 9 are generic to Groups II and III and claim 12 is generic to groups IV and V. These claims will be examined only to the extent that they read on the elected invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: In Group I, the methods of treatment claimed are drawn to four patentably distinct species, propylthiouracil, methimazole, carbimazole and radiolabeled iodide.

If Applicant should elect Group I, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 and 15-23 are generic to Group I.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
July 17, 2002

Karen A. Lacourciere
PATENT EXAMINER